

OCT 27 2011



510(k) SUMMARY

Zimmer Spine  
inViZia™ Anterior Cervical Plate System

510(k) Number K111796

**Date of Summary Preparation:** August 29, 2011

**Manufacturer:** Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439  
USA

**Company Contact:** Elsa Linke  
Regulatory Affairs  
Telephone: 952.832.5600

**Device Name:** inViZia™ Anterior Cervical Plate System

**Common Name:** Spinal Fixation System

**Classification Name:** Spinal Invertebral Body Fixation Orthosis

**Product Code:** KWQ

**Regulation Number:** 21 CFR 888.3060

**Device Classification:** Class II

**Predicate Devices:** Zimmer Spine Trinica® Select Anterior Cervical Plate System (K022344)

Synthes® Spine Anterior CSLP System (K030866 and K971883)

**Description of Device:**

The inViZia™ Anterior Cervical Plate System is a temporary implant system used to facilitate the biological process of spinal fusion. This system consists of plates, screws and instruments and is intended for anterior use in the cervical spine. Surgical instruments are provided to facilitate placement of the implants.

The implants consist of plates of varying length, fixed and variable screws of varying diameter and length. Components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F-136.

This system is intended to provide stabilization until a solid spinal fusion develops. The system may then be removed, per the surgeon's discretion.

**Intended Use:**

The inViZia™ Anterior Cervical Plate System is designed for anterior interbody screw fixation of the cervical spine at levels C2-T1.

The inViZia™ Anterior Cervical Plate System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis and/or failed previous fusions.

**WARNING:** This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**Comparison of Technological Characteristics:**

The inViZia™ Anterior Cervical Plate System shares technological characteristics similar to the predicate devices. These characteristics include similar design, the same materials, same range of sizes, substantially equivalent performance characteristics and the same intended use. Determination of substantially equivalent performance characteristics in regard to the predicate devices was confirmed through static compression bending, dynamic compression bending and static torsion testing in conformance with the requirements of ASTM F-1717:2010. In addition, validated cleaning and sterilization instructions are provided for the non-sterile components of the system.

**Substantial Equivalence:**

The inViZia™ Anterior Cervical Plate System is substantially equivalent to the predicate devices in design, materials, biocompatibility, mechanical performance and indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

OCT 27 2011

Zimmer Spine, Inc.  
% Ms. Elsa Linke  
7375 Bush Lake Road  
Minneapolis, Minnesota 55439

Re: K111796

Trade/Device Name: inViZia<sup>TM</sup> Anterior Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: October 17, 2011  
Received: October 18, 2011

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K111796

Device Name: **inViZia™ Anterior Cervical Plate System**

### Indications for Use:

The **inViZia™ Anterior Cervical Plate System** is designed for anterior interbody screw fixation of the cervical spine at levels C2-T1.


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Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K111796